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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,127	05/13/2002	Robert Llewellyn Clancy	BSWV-P01-002	1497

28120 7590 05/18/2006

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,127	CLANCY ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-34 and 36-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34 and 36-39* is/are rejected.

7)☒ Claim(s) *20 and 37* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's have requested reconsideration of the Restriction Requirement of record mailed 3/28/05. The arguments of record have been considered and were found convincing. Claims 20-34 and 36-39 are rejoined.

Amendment Entry

2. Applicants response to the Office Action mailed August 25, 2005 is acknowledged (paper filed 3/1/06). In the amendment filed therein the specification along with claims 21, 28 and 36 were modified. Currently claims 20-34 and 36-39 are pending and under consideration.

3. Objections and/or rejections of record not reiterated herein have been withdrawn.

OBJECTIONS MAINTAINED

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on PTO-1449 has cited the references they have not been considered. See references cited on pages 15-16.

5. The information disclosure statements filed 2/2/03 and filed 2/22/05 have been considered as to the merits before First Action.

Applicants will submit a supplemental Information Disclosure Statement. Accordingly the objection is maintained.

NEW GROUNDS OF REJECTIONS

Claim Objections

6. Claims 20 and 37 are objected to because of the following informalities: Claims 20 and 37 utilize acronyms (see ALTE and SIDS). Although the terms may have art-recognized meanings, it is not clear if applicant intends to claim any prior art definition of the abbreviations. The terms should be defined in their first instance. The initial explanation will convey intended meaning of subsequent abbreviations in the claims. Please define.

Please Note: Claims 22, 24, 27, and 33 are rejection under both 35 USC 102 and 35 USC 103 because they are dependent on both claim 20 and claim 21.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 20, 22, 24, 27, 33 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375).

Stoltenberg et al. teach the measurement of immunoglobulin responses in SIDS (sudden infant death syndrome-SIDS) and ALTE (acute life threatening episodes) in infants. See abstract and page 373 – 2nd column.

The reference discloses that SIDS increases in incidence with respiratory tract infections and it is speculated that the immune response in the respiratory tract might be one possible "trigger mechanism" in SIDS (assessor of susceptibility or development of SIDS). See page 372. IgA, IgG, and IgM were measured in victims. IgA was elevated in both SIDS samples and infants with infections (infectious control) when compared with controls (predetermined standard). IgA was more elevated in infectious samples when compared to SIDS samples. IgA was elevated more so than the other immunoglobulins (IgM and IgG). See page 373 and figure 1.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 23 and 29 (*dependent on claim 20*) are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Gleeson et al. (Pediatric Research, 1993,Vol.33, No.6, pages 554-556).

Please see Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) as set forth above.

Stoltenberg et al. differs from the instant invention in not specifically teaching sample collections up to 2weeks after an upper respiratory tract infection (URTI) or radial immunodiffusion techniques.

However, Gleeson et al. teach a method of measuring SIDS after URTI in an infant. The mucosal immune response was evaluated in saliva samples collected from the SIDS infant 2 days after birth and during weeks 2, 3, 4, 6, and 8 after birth. The IgA levels were measured by electroimmunodiffusion (radial immunodiffusion). A mild respiratory tract infection was diagnosed in the SIDS infant at 3 ½ weeks of age. See page the results showed that little or no levels of IgA were measured in the saliva for the first 3 weeks of life. However the IgA levels increased in the 4th week (after UTRI infection) and continued to rise through the 8th week. The increased was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the method evaluating IgA in radial immunodiffusion assays after URTI as taught by Gleeson et al. to measure IgA of Stoltenberg et al. because Gleeson et al. taught that IgA levels increased after UTRI infection and the radial immunodiffusion procedure exhibited an increase that was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

One of ordinary skill would have been motivated to measure IgA levels at an increased expression (after URTI) because the prior art has shown that IgA expression in infants is low or nonexistent. See Glesson et al. –Analysis of variability page 536.

III. Claims 30-32 (*dependent on claim 20*) are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Rylatt et al. (WO 97/09620).

Please see Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) as set forth above.

Stoltenberg et al. fails to particularly teach immunoglobulin detection (IgA, IgG, or IgM) with a test strip (assay device) allowing for in situ or near subject-assay measurements.

However, Rylatt et al. disclose a test strip device that can be utilized to measure various analyte including antibodies, which encompass immunoglobulins. See page 5 lines 21-28. The device is useful in biological fluids such as saliva. See page 6 lines 24-26.

The device is also taught to be employed at convenient locations including point of care locations (near-subject assays). See page 1 lines 18-23. Further, the test strip assay system is simple and rapid. See page 4 lines 18-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the IgA analysis teachings of Stoltenberg et al. into the test strip device of Rylatt et al. because Rylatt et al. taught that test strip devices allowed for assay processing at convenient locations (page 1 lines 18-23) and the test strip assay system is simple and rapid (see page 4 lines 18-21).

IV. Claim 38 (*dependent on claim 20*) is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Foster et al. (U.S.Patent#4,444,879).

The teachings of Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) are set forth above. However, the reference fails to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

V. Claims 21, 22, 24, 25, 26, 27, 28, 33, 34, 36 and 37 are rejected under 35 U.S.C. 103(a) as being obvious over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211).

Please see Stoltenberg et al. as set forth above.

Stoltenberg et al. differ from the instant invention in not specifically teaching the detection of IgA1 in saliva samples.

However, Friedman et al. teach a method of detecting rotavirus (acute life threatening episodes-ALTEs or sudden infant death syndrome-SIDS) in infants. Total IgA1 and IgA2 (Applicant's other indices or other cellular components) levels were in serum and saliva samples from infants (claim 22) at birth, at 6 weeks of age, and at 12 weeks of age via quantitative ELISA (claim 28). The detection of IgA1 and IgA2 are disclosed to be possibly significant in mucosal immunization and defense of the respiratory and intestinal tracts. See abstract and page 207 1st column 3rd paragraph.

These disorders are taught to include dysregulation of mucosal immunity. The specification teaches that ALTEs and SIDS are involved in mucosal immunity on page 3 lines 1-2.

Both secreted IgA1 and IgA2 measurements and ratios (ration of immunoglobulin levels) were evaluated in normal/control infants (whole unstimulated saliva see tables 1 and 2), in infants who were feed with breast milk or bottle at the time of sampling/subject is not fasting (whole unstimulated saliva see table 3), and after the infants were immunized with a rotavirus vaccine (see table 4). See page 207 2nd column 4th paragraph through page 209.

IgA1 was found to be exclusively produced in infants and was expressed in much higher concentrations at 6 weeks of age when compared to older children and adults (normal population standard). See pages 208 and 209. In this study IgA1 was shown to be expressed early in infant development and useful in detecting retrovirus antibody activity in infants (page 208 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the invention to measure IgA1 (the specific IgA) of Friedman et al. in the method of measuring IgA in SIDS and infectious infants as taught by Stoltenberg et al. because Friedman et al. taught that IgA1 was found to be exclusively produced in infants and was expressed in much higher concentrations at 6 weeks of age when compared to older children and adults (normal population standard). See pages 208 and 209.

One of ordinary skill would have been motivated to measure IgA1 levels because IgA1 was shown to be expressed early in infant development and useful in detecting retrovirus antibody activity (early immune responses)in infants (page 208 2nd column).

VI. Claims 23 and 29 (*dependent on claim 21*) are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) and further in view of Gleeson et al. (Pediatric Research, 1993,Vol.33, No.6, pages 554-556).

Please see Stoltenberg et al. (Pediatric Research, 1992,.Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) as set forth above.

Stoltenberg et al. in view of Friedman et al. differ from the instant invention in not specifically teaching sample collections after an upper respiratory tract infection (URTI) or radial immunodiffusion techniques.

However, Gleeson et al. teach a method of measuring SIDS after URTI in an infant. The mucosal immune response was evaluated in saliva samples collected from the SIDS infant 2 days after birth and during weeks 2, 3, 4, 6, and 8 after birth. The IgA levels were measured by electroimmunodiffusion (radial immunodiffusion). A mild respiratory tract infection was diagnosed in the SIDS infant at 3 ½ weeks of age. See page the results showed that little or no levels of IgA were measured in the saliva for the first 3 weeks of life. However the IgA levels increased in the 4th week (after UTRI infection) and continued to rise through the 8th week. The increased was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ the method evaluating IgA in radial immunodiffusion assays after URTI as taught by Gleeson et al. to measure IgA or IgA1 (the specific IgA) of Stoltenberg et al. in view of Friedman et al. because Gleeson et al. taught that IgA levels increased after UTRI infection and the radial immunodiffusion procedure exhibited an increase that was five times higher than the age-related median for 8 week-old infants. See page 555 3rd paragraph.

One of ordinary skill would have been motivated to measure IgA levels at an increased expression (after URTI) because the prior art has shown that IgA expression in infants is low or nonexistent. See Friedman et al. –Discussion page 208-209 and Glesson et al. –Analysis of variability page 536.

VII. Claims 30-32 (*dependent on claim 21*) are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) and further in view of Rylatt et al. (WO 97/09620).

Please see Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) as set forth above.

Stoltenberg et al. in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) fail to particularly teach immunoglobulin detection (IgA1 and IgA2) with a test strip (assay device) allowing for in situ or near subject-assay measurements.

Rylatt et al. disclose a test strip device that can be utilized to measure various analyte including antibodies, which encompass immunoglobulins. See page 5 lines 21-28. The device is useful in biological fluids such as saliva. See page 6 lines 24-26. The device is also taught to be employed at convenient locations including point of care locations (near-subject assays). See page 1 lines 18-23. Further, the test strip assay system is simple and rapid. See page 4 lines 18-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the IgA or IgA1 analysis teachings of Stoltenberg et al. in view of Friedman et al. into the test strip device of Rylatt et al. because Rylatt et al. taught that test strip devices allowed for assay processing at convenient locations (page 1 lines 18-23) and the test strip assay system is simple and rapid (see page 4 lines 18-21).

VIII. Claim 38 (*dependent on claim 21 and claim 37*) is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) and further in view of Foster et al. (U.S.Patent#4,444,879).

The teachings of Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) are set forth above. However, the references fail to teach the assay as a kit.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a micro plate, positive controls, negative controls, standards, and instructions are taught. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the detection assay as taught by Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) in view of Friedman et al. (Clinical and Experimental Immunology, 1996, Vol.103, No.2, pages 206-211) and format them into a kit because Foster et al. teach that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit. Further, the reagents in a kit are available in pre-measured amounts, which eliminates the variability that can occur when performing the assay.

Response to Arguments

Applicants contend that the reference to Friedman et al. does not anticipate the instant invention. This argument was carefully considered and found persuasive. Friedman et al. has been replaced with Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) to both anticipate the instant invention and make the invention obvious.

Examiner clarifies that the following reference to Glesson et al. in Pediatric Research, 1993,Vol.33, No.6, pages 554-556 is the correct reference included in the rejections or record. Glesson et al. (Scandinavian Journal of Immunology) has not to been cited in the rejections.

Applicant argues that the instant invention exemplifies unexpected results wherein IgA or IgA1 were shown to be related to SIDS and/or ALTE. Applicants further argue that the reference to Glesson et al. would lead the skilled artisan to detect IgM instead of IgA. This argument was not found persuasive because Glesson et al. teach elevation in both IgA and IgM levels. See Glesson et al. page 555 3rd paragraph. Also, Glesson et al. have been cited in combination with Stoltenberg et al. who discloses an increase in IgA levels with IgM levels that are slightly lower than IgA in SIDS samples. For example, see page 373.

While a deficiency in a reference may overcome a rejection under 35 USC 103, a reference is not overcome by pointing out that a reference lacks a teaching for which other references are relied. In re Lyons, 364 F.2d 1005, 150 USPQ 741, 746 (CCPA 1967).

Applicants contend that Rylatt et al. fail to bridge the gap between Friedman and the instant invention. This argument was carefully considered and found persuasive. Accordingly, Stoltenberg et al. (Pediatric Research, 1992, Vol.31, No.4, pages 372-375) were added to bridge the gap.

9. For reasons aforementioned, no claims are allowed.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would

like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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